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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/092,237	03/06/2002	Steven T. Boyce	CUT/01	8680

26875 7590 10/21/2003
WOOD, HERRON & EVANS, LLP
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CINCINNATI, OH 45202

EXAMINER

KAUSHAL, SUMESH

ART UNIT	PAPER NUMBER
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1636

3

DATE MAILED: 10/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/092,237

Applicant(s)

BOYCE, STEVEN T.

Examiner

Sumesh Kaushal Ph.D.

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2. 6) ☐ Other: _____

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DETAILED ACTION

Applicant's response filed on 03/06/02 has been acknowledged.

Claims 1-33 are pending and are examined in this office action.

► *Applicants are required to follow Amendment Practice under revised 37 CFR §1.121 (<http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/revamdtprac.htm>).*

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10, 13-29 and 31-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Boyce (Med. Biol. Eng. Comput. 36:791-800, 1998, ref of record).

The invention as claimed is drawn to a skin device comprising cultured epidermal cells and dermal cells cultured on a biocompatible matrix.

Boyce teaches skin substitutes comprising cultured human keratinocytes, fibroblasts, melanocytes and collagen-GAG polymers. With regard to claims 1, 5-6, 10, 13-15, 18-19, 24, 28-29 and 31, the cited art teaches a cultured skin substitute comprising cultured dermal cells on Collagen-GAG matrix, which further provides a lamination layer for cultured keratinocytes. With regard to claims 2, 3, 16-17, 19-20, 25, the cited art further teaches that components of skin substitute include keratinocytes, fibroblasts, endothelial cells, smooth muscle cell, melanocytes, nerve cells, glands and hair follicles (page 792, col. 1, table-1, page 793 fig-1). With regard to claim 4, and 27 the cited art further teaches the use of skin substitutes for burns, scars cutaneous ulcers or congenital anomalies (page 791, col.1 para.1). With regard to claims 7 and 21-22 the cited art further teaches that cells in the skin substitute ranges from culture parenchymal cells (autologous or allogenic) to tissue derivatives (i.e. xenogeneic collagens acellular dermal matrix)

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to synthetic polymers (page 792 col.2 para.1). With regard to claim 8 and 23 the cited art further teaches genetic modification of skin cells (page 797 col.2 para.2-3, page 794 fig-3). With regard to claim 9, 16-17, 26 the cited art further teaches that the skin substitute is capable of providing epidermal barrier, basement membrane, angiogenesis and pigmentation (page 794 col.1 para.1, col.2 para.1; page 795, col.2 para.1). The cited art further teaches the use of non-adherent highly porous dressing that allow both delivery and drainage of wound exude from grafts during the period of engraftment (page 795, col.2 para.1). Thus the cited art clearly anticipate the invention as claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-12 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyce (Med. Biol. Eng. Comput. 36:791-800, 1998; ref of record) as applied to claims 1-10, 13-29 and 31-33 above, and further in view of Boyce (US 5,976,878, 1999, ref of record).

Boyce teaches skin substitutes comprising cultured human keratinocytes, fibroblasts, melanocytes and collagen-GAG polymers. With regard to claims 1, 5-6, 10, 13-15, 18-19, 24, 28-29 and 31, the cited art teaches a cultured skin substitute comprising cultured dermal cells on Collagen-GAG matrix, which further provides a lamination layer for cultured keratinocytes. With regard to claims 2, 3, 16-17, 19-20, 25, the cited art further teaches that components of skin substitute include keratinocytes, fibroblasts, endothelial cells, smooth muscle cell, melanocytes, nerve cells, glands and hair follicles (page 792, col. 1, table-1, page 793 fig-1). With regard to claim 4, and 27 the cited art further teaches the use of skin substitutes for burns, scars cutaneous ulcers or congenital anomalies (page 791, col.1 para.1). With regard to claims 7 and 21-22 the

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cited art further teaches that cells in the skin substitute ranges from culture parenchymal cells (autologous or allogenic) to tissue derivatives (i.e. xenogeneic collagens acellular dermal matrix) to synthetic polymers (page 792 col.2 para.1). With regard to claim 8 and 23 the cited art further teaches genetic modification of skin cells (page 797 col.2 para.2-3, page 794 fig-3). With regard to claim 9, 16-17, 26 the cited art further teaches that the skin substitute is capable of providing epidermal barrier, basement membrane, angiogenesis and pigmentation (page 794 col.1 para.1, col.2 para.1; page 795, col.2 para.1). The cited art further teaches the use of non-adherent highly porous dressing that allow both delivery and drainage of wound exude from grafts during the period of engraftment (page 795, col.2 para.1).

Even though Boyce (1998) teaches a method of making skin substitute comprising variety of cultured cells the reference does not specifically teach a method of producing a cultured skin device in medium containing insulin in the range of 0.05 ug/ml to 500 ug/ml

With regard to claims 11-12 Boyce (US 5,976,878, 1999) teaches a method of making a composite skin on a laminated surface of dermal membrane (collagen-GAG), wherein the human keratinocytes are cultured in a media containing 0.5 ug/ml of insulin (col.14 line 64). With regard to claim 30 the cited art teaches dehydration of collagen matrix to form a cross-linked matrix before inoculation with dermal culture (col.12 line 45-61). Thus it would have been obvious to one ordinary skill in the art at the time of filing to incorporate insulin in the range of 0.05 ug/ml to about 500 ug/ml in the culture conditions as taught by Boyce (1998). One would have been motivated to incorporate insulin in culture media because insulin is a growth factor that increases cellular growth and proliferation. It would have been further obvious to use dehydrated laminated collagen as taught by Boyce (1998). One would have been motivated to make dried cross-lined matrix because such a preparation can be stored in a dry state for future use. Thus the invention as claimed is prima facie obvious in view of cited prior art of record.


Conclusion

No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sumesh Kaushal Ph.D. whose telephone number is 703-305-6838. The examiner can normally be reached on Mon-Fri. from 9AM-5PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned is 703-872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

S. Kaushal
Patent examiner



**JEFFREY FREDMAN
PRIMARY EXAMINER**